HEALTHCARE

JUN - 1 2001 K003973

Fisher & Paykel Healthcare Ltd
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19 December, 2000

510(k) Summary of Safety and Effectiveness Information

Model No. / Name: **HC150 Respiratory Humidifier**

Classification Name: Humidifier, Respiratory Gas (Direct Patient Interface) - 73 BTT Anesthesiology Devices, 21 CFR §868.5450 (Class II)

Predicate Device: Fisher & Paykel, HC100 Respiratory Humidifier, K915460

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) - (a)(3) Refer to information above and concluding this summary.

(a)(4) Description of the Device

The HC150 Humidifier is a Respiratory Gas Humidifier (heated passover type) according to 21 CFR §868.5450. Heat is used to provide an evaporated water content to dry breathing gases.

The HC150 has a thermoplastic enclosure with dimensions of 54mm high × 132mm wide × 146mm deep, and weighs 0.7kg. A heaterplate is positioned in the top of the unit, where the enclosure rim and finger guard allow a humidification chamber to be added. The unit controls are located on the front panel.

Accessories for the HC150 Humidifier include humidification chambers, breathing tubing, and mounting arrangements.
The chamber slides on to the heaterplate and contains the water supply for adding humidity to breathing gases. Breathing tubing transports gases from a CPAP Blower through the chamber and to the patient interface such as a nasal mask.

The HC150 Humidifier controls heaterplate temperature between 30°C and 65°C depending on control setting. Ambient temperature is monitored in order to reduce breathing tube condensation in cooler operating conditions.

(a)(5) Statement of the Intended Use

The HC150 Humidifier is intended to warm and add moisture to the breathing gases for administration to a patient. It is used for patients requiring positive pressure breathing assistance such as Continuous Positive Airway Pressure (CPAP) therapy. The addition of heated humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from use of a CPAP system.

(a)(6) Technological Characteristics Summary

The technological characteristics of the HC150 Humidifier are equivalent to the HC100 Humidifier predicate device listed above.
The HC150 is equivalent in terms of: type (heated passover humidification), configuration (chamber, breathing tubing, mounting arrangements), power usage (same heater system ratings), performance (same temperature and humidity output), control method (electronic), and uses equivalent materials and some common components.
The ambient temperature measurement feature uses the same technology as existing temperature control functions.

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the HC150 Humidifier has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, and performance.

The HC150 meets the requirements of the IEC 60601-1 general electromedical and IEC 60601-1-2 EMC standards, and the relevant USA deviations to these in UL 2601-1. It complies with performance and safety requirements of the ISO 8185 and ASTM F1690 particular standards for humidifiers.

(b)(2) Discussion of the Clinical Tests

Clinical verification studies on the HC150 Humidifier were not required in order to demonstrate the safety, effectiveness, and performance of the device.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the HC150 Humidifier indicates that it meets design and performance functional requirements. The proposed device meets the requirements of international and USA medical electrical equipment standards for safety, and key performance and safety requirements from particular standards for humidification systems.

This information indicates that the HC150 Humidifier is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed: _____ date: 19 Dec 2000

Chris Mander
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Mr. Chris Mander
Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place
East Tamaki
Panmure, Auckland, NEW ZEALAND

Re: K003973
Respiratory Humidifier – Model HC150
Regulation Number: 868.5450
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: April 20, 2001
Received: April 23, 2001

Dear Mr. Mander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

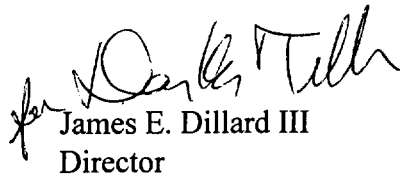
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[510(k)] Number: K003973

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20 April, 2001

Fisher & Paykel Healthcare - HC150 Respiratory Humidifier

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare HC150 Humidifier is a Respiratory Gas Humidifier as per 73 BTT, 21 CFR §868.5450. It is intended to add moisture to and warm breathing gases for administration to a patient.

The HC150 is intended to be used to warm and add humidity to gases delivered to patients requiring positive pressure breathing assistance including Continuous Positive Airway Pressure (CPAP) therapy and Bi-Level Positive Airway Pressure therapy. The HC150 is not for use with auto-titrating positive pressure systems.

The addition of heated respiratory humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from use of a positive airway pressure system.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003973

Prescription Use
(Per 21 CFR §801.109)